DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

g2016d

November 19, 2001

VIA FEDERAL EXPRESS

Jimmy G. Everett, Co-Owner
Everett & Son Seafood
121 Hall Point Road
Sneads Ferry, NC 28460

Warning Letter
02-ATL-09

Dear Mr. Everett:

On August 7-9, 2001, Investigators Robert P. Neligan and James P. Lewis of the Food and Drug Administration (FDA) conducted an inspection of your plant located at Sneads Ferry, North Carolina. During that inspection, our investigators documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your histamine-producing fish to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The HACCP deviations of concern are as follows:

1. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for histamine-producing fish does not list "Storage" as a critical control point (CCP) for controlling the food safety hazard of histamine formation.

2. You must have a HACCP plan that lists the critical limits for each critical control point, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for histamine fish lists a critical limit at the receiving critical control point that is not adequate to control the food safety hazard of histamine formation. For instance, your critical limit of "checking fish for correct temperature" should specify the acceptance temperature at which you will accept the incoming fish. In addition, the critical limit should include a record showing how histamine was controlled by the harvester, since you receive fish directly from the harvester.

3. You also must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan

for histamine fish lists a monitoring procedure at the receiving critical control point that is not adequate to control the food safety hazard of histamine formation. Your monitoring procedure does not specify the method in which you verify incoming fish for correct temperature, i.e. thermometer.

We suggest that you refer to Chapter 7 of the *Fish & Fisheries Products Hazards & Control Guidance: Third Edition, June 2001* (copy enclosed) for guidance in establishing critical limits and monitoring procedures for controlling the hazard of histamine formation in the fish that you process.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Karen Y. Dodson, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mrs. Dodson at (404) 253-1299.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosure